

CENTER FOR DRUG EVALUATION AND RESEARCH

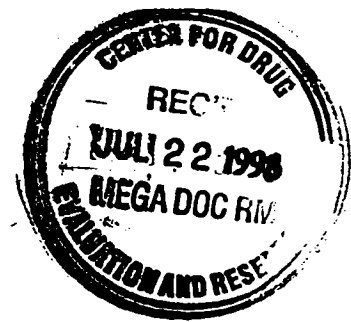
APPLICATION NUMBER: 020634/S04 and 020635/S03

ADMINISTRATIVE DOCUMENTS/CORRESPONDENCE

SNC-004/
DUPLICATE



THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602



JUL 21 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634

LEVAQUIN® Tablets
(levofloxacin tablets)

NDA 20-635

LEVAQUIN® Injection
(levofloxacin injection)

**AMENDMENT TO
PENDING SUPPLEMENTS**

Dear Ms. Anderson:

Reference is made to our approved New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and Injection, respectively. Reference is specifically made to our pending efficacy supplements for uncomplicated urinary tract infections submitted June 4, 1998 (S-004, Tablets; S-003, Injection) and to a July 17, 1998 teleconference in which you requested that we provide you certain information regarding the above said supplements.

Pursuant to your request, we hereby submit the following certifications.

- The R.W. Johnson Pharmaceutical Research Institute certifies that we did not and will not use in any capacity the services of any person debarred under subsections 306(a) or 306(b) of the Federal Food Drug and Cosmetic Act in connection with our above referenced supplemental applications.
- The R.W. Johnson Pharmaceutical Research Institute certifies that the Integrated Summary of Safety contained in the above referenced supplemental applications contains all safety data (foreign and domestic) related to levofloxacin of which we are aware up to the data cut-off of December 19, 1997.

JUL 21 1998

We apologize for inadvertently omitting these certification from the supplemental applications. Should you have any questions or comments, please contact me directly at (908) 704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

The R.W. Johnson
Pharmaceutical Research Institute



Wayne Napoliello
Manager
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

Desk copy: Ms. R. Anderson (N438)

APPEARS THIS WAY
ON ORIGINAL

EXCLUSIVITY SUMMARY FOR NDA # 20-634, S004 and 20-635, S003

Trade Name: Levaquin tablets and injection

Generic Name: levofloxacin

Applicant Name: RW Johnson HFD # 590

Approval Date If Known: 12/ /98

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA? YES /___/ NO /X/

b) Is it an effectiveness supplement? YES /X/ NO /___/

If yes, what type? (SE1, SE2, etc.) SE1

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.") YES /X/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES /___/ NO /X/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety? No

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such) YES /___/ NO /X/

If yes, NDA # _____. Drug Name _____.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /X/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered

(not previously approved.) YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation. YES /X/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement? YES /X/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application? YES /___/ NO /X/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO. YES /___/ NO /___/
If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product? YES /___/ NO /X/

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Protocol # LOFBO-UTI-060

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES ___/ NO /X/

Investigation #2 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NO /X/

NO / /

(continued)

Protocol # LOFBO-UTI-060

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

IND YES /X/ NO /___/ Explain: _____

IND # YES / / NO / / Explain: _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest

provided substantial support for the study? N/A

Investigation #1

YES /___/ Explain _____ NO /___/ Explain _____

Investigation #2

YES /___/ Explain _____ NO /___/ Explain _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /X/

If yes, explain: _____

/S/

Signature: _____ Date: 12/10/98

Title: Project Manager

Signature of Office/Division Director: _____

/S/

Date: 12/17/98

cc: Original NDA

Division File HFD-93 Mary Ann Holovac

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA
Number: 20634 Trade Name: LEVAQUIN(LEVOFLOXACIN) TABS
Supplement
Number: 4 Generic Name: LEVOFLOXACIN TABS
Supplement Type: SE1 Dosage Form: TAB
Regulatory Action: Proposed
Indication: Uncomplicated urinary tract infection

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION? NO

What are the INTENDED Pediatric Age Groups for this submission?

 NeoNates (0-30 Days) Children (25 Months-12 years)
 Infants (1-24 Months) Adolescents (13-16 Years)

Label Status
Formulation Status
Studies Needed
Study Status

APPEARS THIS WAY
ON ORIGINALAre there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:
Not intended for pediatric use.

APPEARS THIS WAY
ON ORIGINAL

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY
OFFICER ROBIN ANDERSON

Signature

Date

12/4/98APPEARS THIS WAY
ON ORIGINAL

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA
Number: 20635 Trade Name: LEVAQUIN(LEVOFLOXACIN INJ) IV
Supplement
Number: 3 Generic Name: LEVOFLOXACIN INJ
Supplement Type: SE1 Dosage Form: INJ
Regulatory Action: Proposed
Indication: Uncomplicated urinary tract infection

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION? NO

What are the INTENDED Pediatric Age Groups for this submission?

 Neonates (0-30 Days) Children (25 Months-12 years)
 Infants (1-24 Months) Adolescents (13-16 Years)

Label Status
Formulation Status
Studies Needed
Study Status

APPEARS THIS WAY
ON ORIGINALAre there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? YES NO

COMMENTS:

Not intended for pediatric use.

APPEARS THIS WAY
ON ORIGINALThis Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER,
ROBIN ANDERSON

Signature

/S/

Date

12/4/98

APPEARS THIS WAY
ON ORIGINAL



THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202 P.O. BOX 300 RARITAN NEW JERSEY 08862-0600

DEC 01 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

Please cross refer to:

NDA 20-635
LEVAQUIN® Injection
(levofloxacin injection)

RESPONSE TO FDA
REQUEST FOR INFORMATION
RE: ENVIRONMENTAL
ASSESSMENT FOR
S-004 (NDA 20-634) AND
S-003 (NDA 20-635)

Dear Sir/Madam:

Reference is made to our New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and LEVAQUIN Injection, respectively. Reference is specifically made to our LEVAQUIN efficacy supplements for uncomplicated urinary tract infections filed to the above-mentioned NDAs on 4 June 1998 and also to a 30 November 1998 telephone request from Nancy Sager regarding the environmental assessment provided on 28 October 1998 for these supplements.

At this time, we wish to confirm that the assessment provided on 28 October 1998 will serve as the FOI copy, as a confidential version was not submitted. In addition, we are providing an update to correct a typographical error to the last sentence of the second paragraph of Section IV. Proposal Action.

Should you have any questions and/or comments, please contact me at 908-704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

Wayne Napoliello
Manager
Regulatory Affairs

cc: Ms. Robin Anderson (S438)
Ms. Nancy Sagar (provide via fax)



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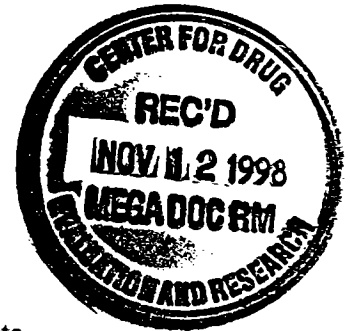
THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0300

NEW CORRESP

NC

NOV 11 1998



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

Please cross refer to:

NDA 20-635
LEVAQUIN® Injection
(levofloxacin injection)

APPEARS THIS WAY
ON ORIGINAL

RESPONSE TO FDA
REQUEST FOR MICROSOFT
ACCESS DATABASE

Dear Dr. Sacks:

Reference is made to our approved New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and Injection, respectively. Reference is also made to the 20 October 1998 CANDA training session regarding our pending efficacy supplements for uncomplicated urinary tract infections and to your request for this database in an electronic Microsoft Access format.

As per your request, enclosed please find a CD containing the Microsoft Access database utilized in our supplements. These tables were created from the SAS database and therefore the table structure is a replica of the SAS data references in the Appendix to the CANDA User's Manual. Please refer to this manual for detailed information pertaining to naming conventions and field content.

We are unable, however, to assist you with setting a WORD default that would keep your pasted graphic fixed on the page.

APPEARS THIS WAY
ON ORIGINAL

Should you have any questions specifically related to the CANDAs, please call Cindy Hardiman at (908) 704-4583. For any other questions and/or comments, please contact me at 908-704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

The R.W. Johnson
Pharmaceutical Research Institute



Wayne Napoliello
Manager
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

Desk copies: Dr. L. Sacks (S435) with CD ROM
Ms R. Anderson (S438)

APPEARS THIS WAY
ON ORIGINAL



THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

DUPLICATE
NDA SUPPL AMENDMENT
SEI-004/BC

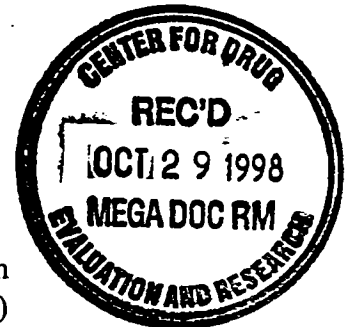
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Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

Please cross refer to:

NDA 20-635
LEVAQUIN® Injection
(levofloxacin injection)



APPEARS THIS WAY
ON ORIGINAL

RESPONSE TO FDA
DEFICIENCY LETTER RE:
S-004 (NDA 20-634) AND
S-003 (NDA 20-635)

Dear Sir/Madam:

Reference is made to our New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and LEVAQUIN Injection, respectively. Reference is specifically made to our LEVAQUIN efficacy supplements for uncomplicated urinary tract infections filed to the above-mentioned NDAs on 4 June 1998 and also to a 21 July 1998 facsimile correspondence from Ms. Robin Anderson regarding deficiencies in the environmental assessment provided in these supplements (please see attached facsimile).

At this time, we wish to provide the appended environmental assessment report in response to the deficiency letter. We trust that this document provides all the requested information.

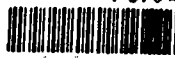
Should you have any questions and/or comments, please contact me at 908-704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

Wayne Napoliello
Manager
Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

cc: Ms. Robin Anderson (S438)

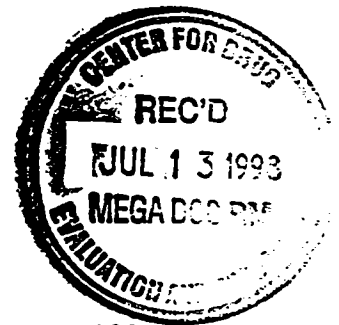


NC
NEW CORRESP

ORIGINAL

THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0502



JUL 10 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

MEMORANDUM OF
UNDERSTANDING

APPEARS THIS WAY
ON ORIGINAL

Dear Sir/Madam:

Reference is made to our approved New Drug Application 20-634 for LEVAQUIN® Tablets. Reference is also made to a May 27, 1998 submission requesting review of a proposed stability matrix for a new LEVAQUIN dosage form and a June 11, 1998 follow-up telephone call from Dr. Holbert from the FDA responding to our request.

At this time, we wish to submit a draft memorandum of understanding summarizing the substance of Dr. Holbert's response according to provision 21 CFR 10.65.

We have appended a copy of this memorandum and would appreciate receiving your written agreement to this document.

Should you have any questions and/or comments, please contact me directly at (908) 704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

APPEARS THIS WAY
ON ORIGINAL

Wayne Napoliello
Manager
Regulatory Affairs

Attachment

Desk copy: Ms. R. Anderson (N438)
Dr. G. Holbert (N433)



THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, PARITAN, NEW JERSEY 08665-0502

NC
NEW CORRESP
ORIGINAL

JUN 30 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

Please cross refer to:

NDA 20-635
LEVAQUIN® Injection
(levofloxacin injection)

APPEARS THIS WAY
ON ORIGINAL

Dear Ms. Anderson:

Reference is made to our approved New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and LEVAQUIN Injection, respectively. Reference is also made to your June 29, 1998 request to provide an additional hard copy of several volumes from our supplemental NDA submitted to the above referenced applications on June 4, 1998.

Pursuant to your request, we are providing a copy of volumes 5, 24, and 25 from our pending supplemental NDA directly to your attention.

Should you have any questions and/or comments, please contact me at 908-704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

Wayne Napoliello
Manager
Regulatory Affairs

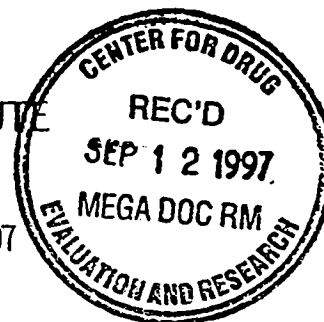
APPEARS THIS WAY
ON ORIGINAL

Attachments directly to Ms. Robin Anderson (N445)





THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602



SEP 11 1997

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV, HFD-590
Attn: Document Control Room
9201 Corporate Blvd.
Rockville, Maryland 20850

NDA 20-634
LEVAQUIN® Tablets
(levofloxacin tablets)

Please cross refer to:

NDA 20-635
LEVAQUIN® Injection
(levofloxacin injection)

EFFICACY SUPPLEMENT
FORMAT PROPOSAL
FOR REVIEW AND COMMENT

Dear Sir/Madam:

Reference is made to our New Drug Applications 20-634 and 20-635 for LEVAQUIN Tablets and LEVAQUIN Injection, respectively. At this time, we are submitting a filing strategy for efficacy supplements that will support the use of LEVAQUIN Tablets and LEVAQUIN Injection in the treatment of uncomplicated urinary tract infections. We are planning to file these supplements in 1Q98.

The supplements will be supported by one adequate and well controlled phase 3 study, LOFBO-UTI-060 "A Multicenter, Double-Blind, Randomized Study to Compare the Safety and Efficacy of Oral Levofloxacin with that of FLOXIN® in the Treatment of Uncomplicated Urinary Tract Infections in Women". In addition, pharmacokinetic/dynamic (pk/pd) data, demonstrating urinary levofloxacin levels exceed the expected MIC₉₀ of claimed pathogens, will be included. All information/data, with the exception of the LEVAQUIN Injection package insert, will be contained in the tablet supplement. The injection supplement will contain the injection package insert and will cross-refer to the information/data in the tablet supplement.

We have appended our format proposal for your review and comment. The proposal includes a draft table of contents for the tablet and injection supplements with specific items for FDA consideration. Once comments are received from your Division, we will use the principles of this proposal for future efficacy supplements.

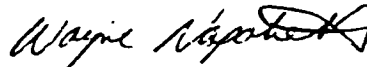
BEST POSSIBLE COPY

We respectively request a meeting or teleconference to discuss the Agency's comments on our proposal and we will telephone Ms. Anderson on September 26, 1997 to schedule a convenient date. Should you have any questions and/or comments, please contact me at 908-704-4879 or call our telephone line dedicated for FDA use at (908) 704-4600.

Very truly yours,

The R.W. Johnson
Pharmaceutical Research Institute

APPEARS THIS WAY
ON ORIGINAL



Wayne Napoliello
Manager
Regulatory Affairs

Desk Copy: Ms. Robin Anderson (N445)
Dr. Robert Hopkins (S345)

APPEARS THIS WAY
ON ORIGINAL

MEMORANDUM OF TELECON

DATE: 12/10/98

APPLICATION NUMBER: NDA 20-634, S004 and 20-635, S003; (Levaquin)

BETWEEN:

Name: Mary Ellen Zamstein, Paula Norwood, Nancy Morgan, Heather Jordan, Yolanda Mauriz, Katherine Reilly-Gauvin, Kimberly Edwards-Swanson, Karen Bush, Cynthia Fowler

Phone: (908) 704-5883

Representing: R. W. Johnson Pharmaceutical Research Institute

AND

Name: Robin Anderson, Robert Hopkins, Leonard Sacks, Peter Dionne
Division of Special Pathogen and Immunologic Drug Products, HFD-590

SUBJECT: FDA's proposed labeling revisions for this application

- On 12/8/98 a fax was sent to the company including summaries of patients with admission cultures for *Proteus mirabilis*, *Enterococcus faecalis*, *Staphylococcus saprophyticus* and *Klebsiella pneumoniae*. The company was advised that the number of suitable isolates for *Proteus mirabilis* and *Enterococcus faecalis* were not sufficient to support a claim for these two organisms. The company agreed with FDA's conclusion.
- FDA advised the company that references to "Group A" and "Group B" in the Microbiology and Indication and Usage sections should be deleted.
- The company will FEDEX their revised label to FDA today. The company was advised that an approval letter would probably be sent next week.

/S/

Robin Anderson
Project Manager

cc: Original NDA 20-634 and 20-635
HFD-590/Div. File
HFD-590/R. Anderson
HFD-590/R. Hopkins
HFD-590/L. Sacks
HFD-590/P. Dionne

Concurrence:

HFD-590/R. Hopkins

/S/
12/11/98

TELECON